Clinical practice guidelines for oral management of Sjögren disease

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Salivary dysfunction can have serious adverse effects on the oral health of patients with Sjögren disease (formerly known as Sjögren syndrome), making it paramount that the oral clinician uses every means possible to prevent complications. Patients with Sjögren disease have significantly higher levels of dental caries, require more tooth extractions, and report higher dental expenses over their lifetime than do controls. Sjögren disease clearly is associated with a high burden of disease, including diminished quality of life and increased health care costs, especially high dental care costs. Sjögren disease is the second most common autoimmune connective tissue disease, affecting up to 3.1 million Americans according to the National Arthritis Data Workgroup, or approximately 1 in 70 people. This number represents those with Sjögren disease alone (traditionally referred to as primary Sjögren disease); the number affected approximately doubles if those with another major autoimmune or rheumatic disease in addition to Sjögren disease are included. Although

ABSTRACT

Background. Salivary dysfunction in Sjögren disease can lead to serious and costly oral health complications. Clinical practice guidelines for caries prevention in Sjögren disease were developed to improve quality and consistency of care.

Methods. A national panel of experts devised clinical questions in a Population, Intervention, Comparison, Outcomes format and included use of fluoride, salivary stimulants, antimicrobial agents, and nonfluoride remineralizing agents. The panel conducted a systematic search of the literature according to pre-established parameters. At least 2 members extracted the data, and the panel rated the strength of the recommendations by using a variation of grading of recommendations, assessment, development, and evaluation. After a Delphi consensus panel was conducted, the experts finalized the recommendations, with a minimum of 75% agreement required.

Results. Final recommendations for patients with Sjögren disease with dry mouth were as follows: topical fluoride should be used in all patients (strong); although no study results link improved salivary flow to caries prevention, the oral health community generally accepts that increasing saliva may contribute to decreased caries incidence, so increasing saliva through gustatory, masticatory, or pharmaceutical stimulation may be considered (weak); chlorhexidine administered as varnish, gel, or rinse may be considered (weak); and nonfluoride remineralizing agents may be considered as an adjunct therapy (moderate).

Conclusions and Practical Implications. The incidence of caries in patients with Sjögren disease with dry mouth were as follows: topical fluoride should be used in all patients (strong); although no study results link improved salivary flow to caries prevention, the oral health community generally accepts that increasing saliva may contribute to decreased caries incidence, so increasing saliva through gustatory, masticatory, or pharmaceutical stimulation may be considered (weak); chlorhexidine administered as varnish, gel, or rinse may be considered (weak); and nonfluoride remineralizing agents may be considered as an adjunct therapy (moderate).

Key Words. Sjögren syndrome; xerostomia; practice guidelines; fluoride; antimicrobial; salivary flow; remineralization.

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Supplemental material is available online.
Sjögren disease is a systemic disease and can affect any body organ or system, dry mouth and dry eyes are chief symptoms.4,9 Sjögren disease causes chronic inflammation and dysfunction and, ultimately, damages the salivary glands.

The Sjögren’s Syndrome Foundation (SSF) set about establishing the first-ever clinical practice guidelines for Sjögren disease to improve consistency and quality of care for assessing and managing the disease. It is critical for oral health care professionals to identify patients potentially having Sjögren disease and ensure that they obtain a correct diagnosis and start appropriate management to prevent caries. Care must be coordinated by a team of health care professionals that includes a dentist, rheumatologist, and ocular specialist. The SSF clinical practice guidelines for caries prevention address clinical questions pertaining to the use of fluoride, salivary stimulants, antimicrobial agents, and nonfluoride remineralizing agents.

METHODS
The SSF followed a highly transparent and rigorous process in developing clinical practice guidelines. Guideline protocols and principles were based on those defined by the American College of Rheumatology, the Institute of Medicine, and the Appraisal of Guidelines for Research and Evaluation and involved participation by the American Dental Association (ADA) evidence-based dentistry staff.10-13 Overarching methodological principles were transparency, involvement of key stakeholders, and consistency. All participants completed American College of Rheumatology conflict of interest forms.

Methodological process. We established topic review groups (TRGs) for each caries prevention topic. To reduce bias as much as possible, we predefined all methodology elements, starting with completion of guidelines protocol worksheets (Appendix 1, available online at the end of this article) for each TRG that delineated clinical questions in the patient population, intervention, comparison, outcome format and defined parameters for literature searches and data extraction for all selected articles. The ADA conducted a systematic literature search by using predetermined terms and parameters. A minimum of 2 TRG members reviewed all abstracts and selected articles for further review. See the Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagrams, Figures 1 through 4,14 for literature search details. Appendix 2 (available online at the end of this article) provides search terms. An ADA guidelines expert and librarian (S.T.) executed the systematic literature search.

We prepared data extraction tables that included details on study characteristics, sample and disease information, evidence, and study quality for each publication (Appendix 3, available online at the end of this article). At least 2 TRG members extracted the data, and the TRG as a whole rated the strength of the evidence, developed a draft recommendation, and rated the strength of the recommendation. We based grading of the evidence and strength of the recommendation largely on grading of recommendations, assessment, development, and evaluation,15 which rates the quality of the evidence on the basis of study limitations, inconsistency of results, indirectness of evidence, imprecision, and publication bias (very low quality to high quality). We rated the strength of the recommendation on the basis of quality of evidence, balance of benefits and harms, values and preferences, and costs (strong or weak both for and against). For the strength of the recommendation, we used a variation of grading of recommendations, assessment, development, and evaluation that was developed by the American Society of Clinical Oncology.16 (Appendix 4 provides definitions used for the strength recommendations, and Appendix 5 provides the guidelines statement regarding decision on grading the quality of evidence; available online at the end of this article).

We followed a Delphi-type process to ascertain level of agreement from practitioners and other stakeholders before finalizing recommendations. The TRGs summarized the data and rationale for the recommendations they drafted, and we provided these documents (Appendix 6, available online at the end of this article, provides clinical rationales and evidence summaries), the data extraction tables, and a summary outlining the process to the consensus expert panel (CEP) that reviewed the recommendations. The CEP, made up of key stakeholders (listed in Appendix 7, available online at the end of this article), voted on each recommendation by using a 6-point Likert scale with the following ratings: completely agree, mostly agree, slightly agree, slightly disagree, mostly disagree, and completely disagree. Forty-two to 45 CEP members voted and added comments for TRG consideration. A minimum of 75% agreement was required and clearly met with 1 round of voting for each topic. However, because of comments received on the strength of the recommendation on fluoride, a second round of consensus was held for this specific question, leading to CEP agreement to increase the level for the strength of the recommendation. Participants included dentists and dental hygienists from academia and community practice, oral medicine experts, clinical researchers, and patients with Sjögren disease.

Appendix 8 (available online at the end of this article) provides the CEP votes.

**CHALLENGES**

Numerous challenges existed in the development of the recommendations. The dearth of studies meeting pre-selected criteria meant there were few available studies to inform the committee. The oral working group accepted any published criteria for diagnosing Sjögren disease, meaning that comparing study populations was difficult because diagnosis was made according to different clinical or classification criteria. The TRGs considered studies involving patients without Sjögren disease with xerostomia to inform discussions better. Finally, the lack of consistency in outcome measures and the way they were assessed made comparison of the studies difficult.

**CLINICAL QUESTIONS AND RECOMMENDATIONS**

The table presents clinical (population, intervention, comparison, outcome) questions, recommendations for caries prevention in patients with Sjögren disease, and the strength of each recommendation.

**CLINICAL RATIONALES AND EVIDENCE SUMMARIES**

View the full clinical rationale and evidence summaries for all topic areas provided to the CEPs.
in Appendix 6 (available online at the end of this article).

**FLUORIDE**

Although evidence is greatly limited on the effectiveness of any intervention available to manage dry mouth, more evidence exists to encourage use of topical fluoride in patients with dry mouth than any other tool available. Therefore, the TRG recommends the use of topical fluoride as a first line of defense in patients with Sjögren disease who have dry mouth. The TRG declined to make a recommendation about preferred topical fluorides or frequency of use because of lack of evidence. The latter also would depend on the types (brush on, gel, rinse, or varnish) of fluoride used and individual assessment for caries risk; a baseline recommendation already is provided with fluoride products. In the studies from which we extracted data, most used fluoride daily.

A review of all 136 abstracts found in the systematic literature review led to the final selection of 13 studies that we determined to be relevant to the clinical question and that also met the preset study parameters. Despite the high number of studies available, the evidence for fluoride use is weak because investigators in only 1 study of the 13 looked specifically at patients with Sjögren disease. Investigators in 9 studies focused on patients undergoing head and neck radiation and in 3 on other causes of dry mouth.

The only study including patients with Sjögren disease was published by Hay and Thomson in 2002. In the trial, they compared the effectiveness of casein derivative and calcium phosphate (CD-CP) with sodium fluoride in
138 patients with dry mouth, 56 from Sjögren disease and 82 from radiation therapy. They assessed coronal and root caries as primary outcomes, and follow-up data collection took place 1 year later. They did not specify diagnostic criteria for Sjögren disease, and results were not statistically significant, although the caries incidence was slightly lower in the CD-CP group. The TRG designated the study quality as moderate with an intermediate risk of bias.

Dreizen and colleagues were the first to demonstrate that patients with xerostomia due to head and neck radiotherapy could prevent caries with daily use of topical fluoride gel. The profound benefit of using fluoride was evident whether the patient followed a cariogenic diet or not. Although determined to be of weak quality with high risk of bias by today’s standards, this seminal study brought widespread recognition of the importance of fluoride. Investigators in 3 additional studies in patients undergoing head and neck radiation concluded that fluoride was beneficial for caries prevention; all were rated of moderate quality with intermediate risk of bias. Three remaining studies were deemed of weak quality with high risk of bias.

Three additional studies involved patients with xerostomia from other causes, including those with medication-induced xerostomia, elderly people who were institutionalized, and patients with unclassified xerostomia. The first 2 studies were rated of moderate quality and intermediate risk of bias and the third of weak quality with high risk of bias. Results from all 3 showed fluoride beneficial.
We included 2 studies for data extraction and discussion, but we did not include them in the final selection for evidence. We did not include the Papas and colleagues25 article from 1999 because it was underpowered and an interim analysis, and the TRG included the final results later published as Papas and colleagues in 2008. The second study the TRG eliminated (Al-Joburi and colleagues26) was rated as low quality with high risk of bias, and the TRG noted that the test product currently is not marketed and is of little value to the clinician.

We identified 1 study after an updated literature search conducted April 21, 2015. This study involved elderly people with disabilities living in nursing homes (Ekstrand and colleagues30). Although this study was not included in developing the fluoride recommendation and does not meet the predefined inclusion criteria because of its 8-month duration, it provides some evidence for the use of high fluoride concentration toothpaste in an elderly population, some of whom had oral dryness.

**Fluoride: strength of the recommendation.** The TRG originally rated the strength of the recommendation as moderate. While acknowledging that evidence is weak, the TRG also recognized that more evidence exists demonstrating the benefit of fluoride in patients with dry mouth than any other intervention. Accordingly, the TRG upgraded the strength of the recommendation to strong on the basis of CEP comments and TRG high confidence that the recommendation reflects best practice on the basis of the following: good evidence exists for a true net effect (that is, benefits exceed harms) for fluoride use in dry mouth, the compelling consideration that expert experience and studies outside of Sjögren...
disease indicate that fluoride is highly effective in preventing caries in dry mouth, and the extent of agreement by the TRG and CEP that the recommendation meets the SSF’s clinical practice guidelines definition for making a strong recommendation.

**SALIVARY STIMULATION**

Reduction in salivary gland function, lack of oral clearance, and reduced amounts of bioavailable calcium and phosphate place patients with Sjögren disease at increased risk of demineralization of teeth and development of dental caries and erosion. Reduction in salivary output is regarded as a key component of any comprehensive assessment for caries risk assessment.\(^3\)

Salivary stimulation: strength of the recommendation. Of 136 unique articles found in the literature review, the salivary stimulation TRG found none that addressed its clinical question. As a result, the strength of the recommendation was rated as weak. CEP members noted, however, that salivary stimulation for caries prevention in patients with Sjögren disease with dry mouth is accepted widely and should be recognized as a core therapeutic measure on the basis of strong anecdotal evidence and clinical experience.

**ANTIMICROBIAL AGENTS**

In addition to the decline in salivary flow rate, changes in the composition of saliva alter its antimicrobial properties and lead to an accumulation of oral pathogens, resulting in severe tooth decay and tooth loss, even with proper oral hygiene. After reviewing 136 abstracts, we selected for data extraction 9 studies in which the investigators examined the efficacy of antimicrobial agents. A subsequent decision to restrict the intervention agent to chlorhexidine reduced the number of relevant studies to 3. None of these studies involved patients with Sjögren disease as the study population.

Results of the first study, a multicenter randomized clinical trial,\(^2\) indicated that both root caries and total caries were reduced significantly in the chlorhexidine group compared with placebo. Coronal caries also were reduced, but the difference between the 2 groups did not reach statistical significance. The investigators reported no significant differences in caries increment between the chlorhexidine and placebo groups, a finding attributed to unanticipated antimicrobial properties of the placebo treatment.

Investigators in a second randomized controlled trial\(^2\) examined the efficacy of chlorhexidine-thymol varnish in a sample of 102 frail elderly patients with root

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**TABLE**

<table>
<thead>
<tr>
<th>TOPIC AREA</th>
<th>CLINICAL QUESTIONS AND RECOMMENDATIONS</th>
<th>STRENGTH OF RECOMMENDATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoride</td>
<td>Clinical Questions:</td>
<td>Strong</td>
</tr>
<tr>
<td></td>
<td>1. In patients with primary Sjögren disease, does the use of a topical fluoride compared with no topical fluoride reduce the incidence, arrest, or reverse coronal or root caries?</td>
<td>Weak</td>
</tr>
<tr>
<td></td>
<td>2. In patients with primary Sjögren disease, is one topical fluoride agent more effective than another in reducing the incidence, arresting, or reversing coronal or root caries? (No information available to answer the second question.)</td>
<td>Weak</td>
</tr>
<tr>
<td></td>
<td>Recommendation: Topical fluoride should be used in patients with Sjögren disease with dry mouth.</td>
<td>Weak</td>
</tr>
<tr>
<td>Salivary Stimulation</td>
<td>Clinical Questions:</td>
<td>Weak</td>
</tr>
<tr>
<td></td>
<td>1. In patients with Sjögren disease, does stimulating saliva flow compared with not stimulating saliva flow reduce the incidence, arrest, or reverse coronal or root caries?</td>
<td>Weak</td>
</tr>
<tr>
<td></td>
<td>Recommendation: Although no studies to date link improved salivary function in patients with Sjögren disease to caries prevention, the oral health community generally understands that increasing saliva may contribute to decreased caries incidence. On the basis of its expert opinion, the topic review group recommends that patients with Sjögren disease with dry mouth increase saliva through gustatory or masticatory stimulation and pharmaceutical agents—for example, sugar-free lozenges or chewing gum, xylitol, mannitol, and the prescription medications pilocarpine hydrochloride and cevimeline.</td>
<td>Weak</td>
</tr>
<tr>
<td>Antimicrobial Agents</td>
<td>Clinical Questions:</td>
<td>Weak</td>
</tr>
<tr>
<td></td>
<td>1. In patients with primary Sjögren disease, does the use of antimicrobial agents compared with placebo reduce the incidence, arrest, or reverse coronal or root caries?</td>
<td>Weak</td>
</tr>
<tr>
<td></td>
<td>Recommendation: Chlorhexidine administered as varnish, gel, or rinse may be considered in patients with Sjögren disease with dry mouth and a high root caries rate.</td>
<td>Weak</td>
</tr>
<tr>
<td>Nonfluoride Remineralizing Agents</td>
<td>Clinical Questions:</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>1. In patients with Sjögren disease, does the use of nonfluoride remineralizing agents compared with placebo reduce the incidence, arrest, or reverse coronal or root caries?</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>2. In patients with Sjögren disease, does the use of nonfluoride remineralizing agents compared with the use of fluoride reduce the incidence, arrest, or reverse coronal or root caries? (Insufficient information available to answer the second question.)</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Recommendation: Nonfluoride remineralizing agents may be considered as an adjunct therapy in patients with Sjögren disease with dry mouth and a high root caries rate.</td>
<td>Moderate</td>
</tr>
</tbody>
</table>
caries. Caries lesions in the placebo group increased significantly and were significantly closer to the gingival margin compared with baseline, but clinical severity of lesions in the test group remained unchanged. The third study was a short-term randomized controlled trial with results that indicated that, although a significant arrest of caries occurred in both groups, the addition of chlorhexidine did not enhance the effectiveness of the fluoride rinse alone.

The TRG declined to include a fourth study in developing its recommendation. Although the investigators in this study reported that chlorhexidine gel in trays was superior to polishing teeth with chlorhexidine in reducing the prevalence of *Streptococcus mutans* in patients with xerostomia—a topic of interest as a secondary outcome—the investigators did not use carious lesions (the TRG’s primary outcome) as an end point. We extracted data for 5 additional studies not used in the final selection for evidence because the required primary outcome was not used.

An additional study by Wyatt and colleagues discovered after the literature search and CEP voting has been added to the evidence summary. In this randomized controlled trial, the investigators concluded that no substantial effect on the preservation of sound tooth structure in older adults resulted from use of a 0.12% chlorhexidine rinse. The study should be recognized, but did not change the recommendation and, in fact, confirmed the strength of the recommendation.

**Chlorhexidine: side effects.** Chlorhexidine mouthrinse has a number of side effects, the most common of which is a brownish staining of the teeth. Staining is reported in up to one-half of patients but is removable once the mouthrinse is discontinued. Chlorhexidine may cause an increase in calculus development. Other less frequently reported side effects include altered taste, which can persist for several hours after use, oral burning, and development of lesions and ulcerations of the gingival mucosa. It also has a strong, unpleasant taste that most patients find objectionable.

**Antimicrobial agents: strength of the recommendation.** Because available evidence for recommending chlorhexidine use for caries prevention is weak, the strength of the recommendation was rated as weak. Although the TRG is confident that the recommendation is valid in the circumstances cited and offers the best guidance for practice, the group’s confidence is diminished by the potential side effects, the experts’ opinions, and the study by Wyatt and colleagues.

**Nonfluoride remineralizing agents:**

Nonfluoride remineralizing agents may be considered for use by patients with Sjögren disease with dry mouth to prevent caries. A review of 136 abstracts led to the selection of 23 studies for data extraction. After thorough review, the TRG decided that only 2 studies met the predetermined criteria for determining the efficacy of nonfluoride remineralizing agents. Investigators in 1 study addressed the clinical question of comparing nonfluoride remineralizing agents versus fluoride; no study investigators examined nonfluoride remineralizing agents versus placebo.

The first study, a randomized but open-label clinical trial, already has been described in the section concerning fluoride. The results were not statistically significant, although the incidence of coronal caries was slightly lower in the CD-CP group. The study investigators concluded that use of CD-CP might hold promise in reducing caries in patients with dry mouth.

The second study was a retrospective cohort study. Patients used a saturated calcium phosphate rinse 3 or 4 times a day with sodium fluoride (1.1% sodium fluoride) at night. The 134 patients included those with Sjögren disease, those with medically induced xerostomia, and those undergoing head and neck radiation. Although fluoride use presented a confounding factor, the TRG noted that the use of prescription-strength fluoride in addition to the calcium phosphate rinse was significantly more beneficial.

We did not include xylitol-containing products in the literature search because they were just coming into use when the guidelines initiative started. Only weak evidence exists for its use in caries prevention. In their 2015 Cochrane review, Riley and colleagues confirmed the weak evidence for xylitol but stated that fluoridated toothpaste with xylitol appeared to be more effective than toothpaste with fluoride alone in preventing caries in the permanent teeth of children.

**Nonfluoride remineralizing agents: strength of the recommendation.** This recommendation was rated as moderate. While acknowledging that the evidence is based on limited studies, the ratings allow for inclusion of the strength of expert opinion (Appendix 4, available online at the end of this article). The TRG concluded that clinicians should consider the use of nonfluoride remineralizing agents as worthy of their attention and consideration. Emphasis is placed on all recommendations for caries prevention in Sjögren disease being viewed in aggregate—that is, the clinician should consider all recommendations as potential therapies to be used as deemed necessary for an individual patient and most likely in conjunction with one another.
summaries of the evidence are available at the ADA Center for Evidence-Based Dentistry website for topical fluoride agents,14 nonfluoride caries preventive agents,15 and pit-and-fissure sealants.46

FUTURE DIRECTIONS FOR RESEARCH

Patients with Sjögren disease with dry mouth must be considered as being at high risk of developing caries, and the need for evidence-based preventive intervention is of paramount importance. On the basis of the extensive literature search, an unexpected lack of well-controlled studies exists that provide scientific evidence for the most effective preventive interventions in this patient population. A need for standardization of clinical outcome measures is critical so that findings across studies can be interpreted properly by using advanced methods such as meta-analyses.

While recognizing the need for clinical trials in patients with Sjögren disease with dry mouth in which investigators evaluate the role of fluoride for caries prevention, the authors also recognize that fluoride remains the criterion standard for preventing caries in patients with xerostomia, and all patients ethically should receive fluoride. No data exist, however, on whether one topical fluoride is more effective than another in preventing caries in patients with Sjögren disease, and the TRG encourages future studies to elucidate any differences. In particular, studies are needed in which the investigators compare professionally applied fluoride products, such as fluoride varnish treatments, with and without added nonfluoride remineralizing agents. Also, assessing the benefits of prescription-strength fluoride toothpaste compared with regular toothpaste in patients with Sjögren disease is necessary. Future clinical trials in patients with Sjögren disease to assess agents to be used as adjuncts to ongoing fluoride clearly are needed to evaluate the role of salivary stimulation products or pharmaceutical agents, chlorhexidine and other antimicrobials, and nonfluoride remineralizing agents.

CONCLUSIONS

Based on limited evidence, incidence of caries in patients with Sjögren disease can be reduced with the use of topical fluoride, and all patients with Sjögren disease should receive fluoride as the first line of therapy. Other preventive strategies, including salivary stimulation, antimicrobials such as chlorhexidine, and nonfluoride remineralizing agents, can be considered as adjunctive treatments. Research studies specifically in patients with Sjögren disease are clearly needed for all of these caries preventive interventions. ■

SUPPLEMENTAL DATA

Supplemental data related to this article can be found at http://dx.doi.org/10.1016/j.adaj.2015.11.008.

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